

AMENDMENT TO THE CLAIMS

Claims 1-22. (Cancelled)

Claim 23. (Previously Presented) A liposomal formulation containing a dinitroaniline pesticidal agent incorporated in a pharmaceutical formulation comprising a mixture of at least two separate and distinct liposome formulations whose populations of particles have mean diameters respectively bigger and lower than 100 nm.

Claim 24. (Currently Amended) The A liposomal formulation according to claim 23, which comprises a mixture of pre defined populations of particles with mean diameters respectively bigger than 400nm and lower than 100nm containing dinitroaniline which comprises two different liposomal populations of particles whose diameters are (i) larger than 400 nm, and (ii) smaller than 100 nm, wherein population (i) is prepared by extrusion through a membrane of successively decreasing pore diameter from 5 μ m to 0.4 μ m; population (ii) is prepared by further treating one half of population (i) by continuing sizing by extrusion through a membrane to a filter of 0.05 μ m; the two populations (i) and (ii) are then mixed together and the resultant mixture is submitted to freezing at - 70° for 60 minutes and thereafter lyophilized; the so-obtained

lyophilized product is recovered and ready for parenteral administration in sterile distilled water.

Claim 25. (Previously Presented) A process for the preparation of a final formulation composed of distinct populations with distinct mean diameters, containing a dinitroaniline pesticide, which comprises the steps:

1. obtaining of the liposomal formulations containing vesicles of dinitroaniline pesticide by hydration, with a solution containing an antisolubilizing agent of a lipidic film containing the dinitroaniline pesticide;
2. Obtaining different populations with well-defined diameters by a sizing step;
3. mixing the distinct populations;
4. lyophilization dehydration of the so obtained liposomal formulations; and
5. rehydration of the dehydrated liposomal formulations.

Claim 26. (Cancelled)

Claim 27. (Previously Presented) The process according to claim 25, which comprises performing the sizing step by extrusion of the vesicles under Pressure through porous membranes.

28. (Previously Presented) The process according to claim 25, wherein the hydration is carried out by the addition of an aliquot portion of an aqueous solution, followed by the addition of the remaining volume of the aqueous solution, after a resting period.

29. (Previously Presented) The process according to claim 28, which comprises using, in the hydration steps, a salt-free solution.

30. (Previously Presented) The process according to claim 29, which comprises performing the rehydration steps with saccharose, trehalose, glucose or mixtures thereof.

Claim 31. (Previously Presented) The process according to claim 25, which comprises mixing at least two different distinct mean diameter particle populations.

Claim 32. (Previously Presented) The process according to claim 25, which comprises mixing particles after sizing to yield a population of particles with diameters of, respectively, bigger and lower than 100 nm.

Claim 33. (Previously Presented) The process according to claim 32, which comprises performing the sizing step by extrusion of vesicles under pressure through a porous membrane.

Claim 34. (Previously Presented) The process according to claim 25, which comprises performing the hydration by addition of a small amount of aqueous solution, namely 20% of the final volume, followed by addition of the rest of the volume, namely 80% of the final volume, after a 30-minute rest period.

35. (Previously Presented) The process according to claim 25, which comprises using in the hydration step a salt-free solution.

36. (Previously Presented) The process according to claim 25, which comprises performing rehydration with a member selected from the group consisting of solutions of saccharose, trehalose, glucose and mixtures thereof.

37. (Previously Presented) The process according to claim 25, which comprises using at least one of the lipids selected from the group consisting of distearoylphosphatidylcholine (DSPC), phosphatidylcholine (PC), cholesterol and cholesterol derivatives, sphingomyelin (SM), dioleoylphosphatidylcholine

(DOPC), dioleoylphosphatidylglycerol (DOPG), phosphatidylglycerol (PG), dimiristoylphosphatidylcholine (DMPC), dipalmitoylphosphatidylcholine (DPPC), gangliosides, ceramides, phosphatidylinositol (PI), phosphatidic acid (PA), dicetylphosphate (DcP), dimiristoylphosphatidylglycerol (DMPG), stearylamine (SA), dipalmitoylphosphatidylglycerol (DPPG) and mixtures thereof.

38. (Previously Presented) The process according to claim 25, wherein the dinitroaniline pesticide is trifluralin.

39. (Previously Presented) A liposomal formulation containing a dinitroaniline pesticide when prepared by a process according to claim 25.

40. (Previously Presented) A method of applying the liposomal formulation as defined according to claim 23 which comprises the treatment of disease in humans or animals, wherein administration of a therapeutic quantity of the liposomal formulation is applied to humans or animals.

Claim 41. (Previously Presented) Method for the preparation of a pharmaceutical composition for the treatment of humans or

animals, wherein a composition is provided containing a therapeutic quantity of the pharmaceutical composition containing the dinitroaniline liposomal formulation prepared according to the process of claim 25.

Claim 42. (Previously Presented) The process according to claim 25, which comprises performing the hydration in step 1 by addition of 5-30% of final volume of aqueous solution, followed by addition of the remainder 70-95% of final volume, after a 30-minute period of rest.